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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSC-187 (1002/257)	1401
21874 7590 07/27/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/935,487

Applicant(s)

RIOUX ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed (5/26/04) in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/23/07 has been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. (5123917). Evard et al. illustrates (Fig. 2' ) a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Evard et al. disclose a covering or what can be interpreted as "webbing" such that the entire device is encapsulated or *covered* by the covering, page 33, lines 8-13. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil can be a biocompatible wire made from steel or nickel titanium, page 34, lines 1-3. The Examiner is also interpreting

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the limitation "webbing between the windings" to be present in the Evard device since the covering is over the windings, it can be considered between the windings. The stent device is capable of being positioned coaxially within the body lumen of a patient.

However, Evard fails to disclose the distance between the windings to be at least about 0.5mm or that the webbing or covering is inner and outer layers adhered together or the specific cross sectional area of the wire. Lee et al. teach a spacing between coils to be greater than 0.5mm col. 5, lines 41-43. Lee et al. also teach (Figs. 3,4) a stent with coils **30** having both inner **10** and outer **20** layers of polymer encapsulate the coil body for physical barrier of blood, col. 3, lines 65-68. Lee also teaches to have the polymer layers adhered together, col. 5 lines 29,30. Lee additionally teaches a cross-sectional area of the wire that falls within the claimed range of  $0.0079\text{mm}^2$  to  $7.1\text{mm}^2$  (col. 5, lines 59-61). It would have been obvious to one of ordinary skill in the art to bond or adhere inner and outer polymer layers on the coil stent and space coil windings at least about 0.5mm and use a wire having a cross-sectional area within  $0.0079\text{mm}^2$  to  $7.1\text{mm}^2$  as taught Lee et al. for the device of Evard such that the desired spacing between windings for flexibility can be established within the layers.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Yachia et al. (5246445). Evard as modified by Lee et al. is explained supra. However, Evard in view of Lee do not disclose the distal and proximal portions of the coil segment include hooks. Yachia et al. teach (Fig. 1a) a stent with hooks **3** at both the proximal and distal ends of the coil body for connection to a delivery system, col. 6,

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lines 13-16. It would have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Evard as modified by Lee et al. such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Lee et al. '917 as applied to claim 1 and further in view of Hachtman et al. (5645559). Evard as modified by Lee et al. is explained supra. Evard does disclose the polymer is elastomeric (page 33, lines 5,6) and that silicone layers can be placed on stents, page 17, lines 21-24. However, Evard in view of Lee do not disclose the polymer being a *low durometer* silicone within the range of 0-60D. Hachtman et al. teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a 30D silicone as taught by Hachtman et al. for the silicone on Evard's stent as modified by Lee et al. such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

***Response to Arguments***

Applicant's arguments with respect to claims 1-4,6-8 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).